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Design consideration for ACL implants based on mechanical loading

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Abstract

This study aims to understand and estimate the forces while the anterior cruciate ligament (ACL) is subjected to loading during stair negotiation. 9 healthy subjects were recruited and asked to negotiate stairs while their motion was captured. An OpenSim model was developed to estimate the ACL length from kinematic data. The forces were estimated using a force/displacement relationship. The peak ACL force was 0.416±0.089 N/BW and was recorded at full extension of the knee while the participants were descending stairs. The forces experienced by the right and left ACL of women were highly significant compared to ACL forces in men and the ACL forces in old people were significantly higher than in younger people. These forces will be used as boundary conditions in a novel finite element model (FEM) to estimate tensile and shear stress levels in the ACL to gain design information to create a tissue engineered ACL implant. The CIRP-Biomanufacturing conference promotes the exchange of knowledge on biodesign and biofabrication in order to develop novel medical devices for improving quality of life. This work is relevant to the conference since it contributes to a better understanding of the mechanical behavior of ACL throughout its range of motion and it is the starting point for the design and manufacture of new ACL implants.

Keywords: Anterior cruciate ligament (ACL); stairs negotiation; in vivo kinematics; knee model; ACL forces; ACL strain.

1. Introduction

Ligament injuries are among the most common health problems. It has been estimated that the incidence of injuries to knee ligaments could be at 2/1000 people per year, of which 90% involve the anterior cruciate ligament (ACL) and the medial collateral ligament (MCL) [1]. In the United States more than 200,000 patients are diagnosed with ACL ruptures every year, of which 175,000 cases of ACL injuries require surgery, whose cost has been estimated at $1 billion annually [2].

The ACL is an intraarticular ligament with poor healing properties; therefore ACL injuries often require a surgical reconstruction. Currently, both biological and synthetic scaffolds are used to repair ligaments, although both of them exhibit serious limitations. Tissue Engineering is presented as an alternative eliminating donor-site morbidity and rejection, and restoring the structure and physiological natural tissue functions using a long-term biodegradable scaffold with similar biological and mechanical properties to natural ligaments [3].

Many researchers are developing new tissue engineered ligament and tendon implants. However, regarding to mechanical characterization, only material properties such as Young's modulus, ultimate tensile strain or tensile stress at yield are considered to discriminate if the scaffold has the appropriate characteristics to be implanted.

As far as the authors know, no connection has been created between mechanical behavior at all ranges of motion and design and development of ligaments based on tissue engineering.

The novelty of this project is trying to understand how this ligament behaves while different activities are performed to study the failure mechanisms on the ACL and to be able to design improved implants according to the forces experienced on these natural fibrous connective tissues.

These forces were estimated through a motion capture system in combination with a musculoskeletal model developed in OpenSim software capable to determine the *in*

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vivo ACL length at each moment and with it the ACL strain and force.

To date many studies with cadaveric knees have been performed [4] for different reasons, for determining parameters such as length or area at the attachment sites of the ligament and for understanding its behaviour under mechanical loading. Although the information provided by these studies is very valuable, they have limitations reproducing the *in vivo* mechanical behaviour of the ACL. Other studies use video and motion capture [5, 6] to understand the ACL injury mechanisms; however they do not assess the ACL length or strain, they merely study joint kinematics. Several experiments have been conducted using strain gauges [7] to evaluate the *in vivo* strain while the patient was performing some rehabilitation exercises (step and cycling), but exercises such as ascending and descending stairs, walking or jumping have not been considered. Finally, experiments with motion capture in combination with biplanar fluoroscopy [8, 9] have been performed to estimate ACL length and strain during walking and jumping but we do not have data for activities such as climbing stairs, running or crossover cutting.

In our opinion, create a reliable and easy to implement methodology to estimate *in vivo* ACL strain and forces capable of being applied in all kinds of activities, would help us not only to design better ligament implants but to prevent injury risks, improve rehabilitation protocols, study graft insertion points in order to reduce failure rates, or design ligaments according to patient's needs.

Therefore, in order to understand the behaviour of the ACL and design improved implants, it is necessary to study its kinematics and kinetics while both high impact maneuvers and daily living activities are performed. 78 % of the ACL injuries are due to noncontact activities and most of them happen on sudden deceleration, while landing from a jump, with cross-over cutting or pivoting [10]. At this stage we have studied the strain and the forces imposed on the ligament while participants ascend and descend stairs; however activities such as walking, running, jumping and cross-over cutting will be performed in future experiments.

In future work, these forces will be used as boundary conditions in our novel Finite Element Model to estimate the tensile and shear stress on the ligament and on our implant at all range of motion and for different activities, to enable comparison and assess our design.

The aim of this early stage of the project is to develop a methodology, applicable in all kind of activities, in order to determine the *in vivo* forces experienced by the ACL, with which we can design through a Finite Element Model improved ligament implants.

2. Methods

2.1. Recruitment of healthy participants

Nine subjects (6 men and 3 women; mean±SD age: 41.4±13years, height: 1.7±0.09 m and mass: 69.3±13.7 kg) were recruited in this study. Each participant was asked to sign a consent form and to complete two questionnaires prior beginning any activity. The questionnaires were the Knee Injury and Osteoarthritis Outcome Score (KOOS) and the Hip Injury and Osteoarthritis Outcome Score (HOOS), and they allow us to assess knee and hip pain/symptoms and to include in the study only the subjects with no history of knee injury, surgery or pain.

2.2. Motion capture

A total of 33 reflective markers were placed on each participant on specific anatomical landmarks of the lower and upper body. In addition, a set of 16 wireless surface electromyography (EMG) sensors (Delsys Inc. Boston, MA, USA) were situated on each subject, recording the activation of the muscles *quadriceps vastus medialis*, *quadriceps rectus femoris*, *quadriceps vastus lateralis*, *tibialis anterior*, *peroneus longus*, *gluteus medius*, *medial hamstrings* and *gastrocnemius medialis* of both legs. The purpose of EMG recordings was to validate the correct behaviour of the muscles in our musculoskeletal model.

Before starting the experiment the 10-camera motion capture system (Vicon 612 system, Oxford Metrics, UK) was calibrated in order to calculate the location and orientation of all the cameras, and the correct operation of the EMG electrodes was checked on each participant.

The experiments were performed over an 8-step experimental staircase. This staircase had standard dimensions and contained four force platforms (Kistler, Switzerland) embedded into the middle steps. The force plates were used to help inform the static optimization solver implemented in OpenSim with the calculation of the muscle activation. A first static trial for subject calibration (scale body segments and align joints) was performed with each subject. This first trial was considered successful when all markers were visualized. Then, the subjects were asked to ascend and descend the staircase at a normal self-selected speed in a step-over-step manner up to a total of three successful trials, while kinematic data were captured and EMG signal and reaction forces were recorder.

Once the data were collected, they were processed in Vicon Nexus 1.8.5. (Vicon Motion Systems Ltd, UK) software and exported to OpenSim 3.2 (Stanford University, Stanford, CA) for further analysis.

2.3. Determination of ACL elongation

A musculoskeletal model was developed based on a lower extremity with back and torso model created by the developers of OpenSim. This model consists of 23 degree of freedom, 12 elements representing the bones and 92 musculotendon actuators.

The anterior cruciate ligaments were added to this model. These were modelled as a nonlinear elastic passive soft tissue, following a straight line path and it was assumed that there was negligible ligament-bone contact. A Thelen2003 muscle [11] model implemented in OpenSim and based on Hill's model [12] was used to simulate the ACL. In order to mimic its passive character, the fibre length was set to zero and the contractile element activation was annulled.

The attachment sites were incorporate to this model using the average values reported in Xu et al. [13] and the placement was verified through Lee et al. [14] and Jordan et